

Applicant: M. Von Herrath  
Application No.: 09/336,672  
Filed: June 17, 1999  
Page 3

*Cancelled*  
6. (Amended) The composition of claim 1, further comprising a nucleic acid sequence encoding a compound selected from the group consisting of a cytokine, a chemokine, an interferon, ligands for lymphocyte receptors, and combination thereof.

*C2*  
8. (Twice Amended) The composition of claim 6 wherein the biological response modifier is IL-4, IL-10, or a combination thereof.

*D*  
9. (Twice Amended) The composition of claim 1, wherein the nucleic acid construct further comprises a regulatory element operatively linked to nucleic acid encoding the at least one epitope or the compound.

*C3*  
11. (Twice Amended) A method for modifying an ongoing immune response in a subject against a self-antigen associated with autoimmune diabetes comprising administering to the subject by peripheral injection an immunomodulatory effective amount of a plasmid expressing a nucleic acid construct encoding at least one epitope from a self-antigen associated with autoimmune diabetes in a pharmaceutically acceptable carrier, wherein transient expression of the epitope in the subject results in a positive regulatory immune response to multiple self-antigens associated with the autoimmune diabetes.

*Cancelled*  
15. (Amended) The method of claim 11, wherein the regulatory immune response prevents increase of the blood glucose level of the subject.

*C4*  
17. (Amended) The method of claim 11, further comprising administering to the subject a nucleic acid sequence encoding a compound selected from the group consisting of a cytokine, a chemokine, an interferon, ligands for lymphocyte receptors, and an interleukin.

*C5*  
19. (Twice Amended) The method of claim 17, wherein the compound is IL-4, IL-10, or a combination thereof.

C5  
C6  
20. (Twice Amended) The method of claim 17, wherein the nucleic acid construct further comprises a regulatory element operatively linked to nucleic acid encoding the at least one epitope or the compound.

C6  
22. (Twice Amended) A method for controlling the blood glucose level in a subject having an ongoing immune response against a self-antigen associated with autoimmune diabetes comprising administering to the subject by peripheral injection, an immunomodulatory effective amount of a plasmid expressing a nucleic acid construct encoding at least one epitope from a self-antigen associated with autoimmune diabetes in a pharmaceutically acceptable carrier, wherein expression of the epitope in the subject results in a positive regulatory immune response against multiple self-antigens associated with the autoimmune diabetes so as to control the blood glucose level of the subject.

C7  
27. (Amended) The method of claim 22, further comprising administering to the subject a nucleic acid sequence encoding a compound selected from the group consisting of a cytokine, a chemokine, an interferon, ligands for lymphocyte receptors, and combinations thereof.

C8  
29. (Twice Amended) The method of claim 27, wherein the compound is IL-4, IL-10, or a combination thereof.

C9  
32. (Amended) The method of claim 11, wherein a single administration of the nucleic acid construct is effective to modify the ongoing immune response.

33. (Amended) The method of claim 22, wherein a single administration of the nucleic acid construct is effective to control the blood glucose of the subject.

34. (Amended) The method of claim 11, wherein the modification of the immune response affects T-cells reactive to multiple antigens associated with autoimmune diabetes.

Applicant: M. Von Herrath  
Application No.: 09/336,672  
Filed: June 17, 1999  
Page 5

C9  
C9  
35. (Amended) The method of claim 11, wherein the modification of the immune response comprises induction of Th2 lymphocytes reactive to the self-antigen.

36. (Amended) The method of claim 11, wherein the modification of the immune response comprises autoreactive T cells specific for at least one antigen associated with autoimmune diabetes whose epitope is not expressed by the plasmid.

37. (New) The method of claim 19, wherein the self epitope is derived from GAD65.

38. (New) The method of claim 29, wherein the self epitope is derived from GAD65.

C10  
39. (New) The method of claim 36, wherein the epitope expressed by the plasmid is derived from insulin B chain and the antigen whose epitope is not expressed by the plasmid is GAD65.